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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/589,074	08/31/2006	Wilm Buhr	27560U	5832	
	34375 7590 11/01/2007 NATH & ASSOCIATES PLLC			EXAMINER	
112 South Wes	t Street		MABRY, JOHN		
Alexandria, VA 22314			ART UNIT	PAPER NUMBER	
			4133		
			MAIL DATE	DELIVERY MODE	
			11/01/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)		
Office Action Comment	10/589,074	BUHR, WILM		
Office Action Summary	Examiner	Art Unit		
	John Mabry	4133		
The MAILING DATE of this communication appo Period for Reply	ears on the cover sheet with the c	orrespondence address		
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 6(a). In no event, however, may a reply be timil apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).		
Status				
1) ☐ Responsive to communication(s) filed on 11 Au 2a) ☐ This action is FINAL. 2b) ☐ This 3) ☐ Since this application is in condition for allowan closed in accordance with the practice under Expression is the condition of th	action is non-final. ce except for formal matters, pro			
Disposition of Claims				
4) Claim(s) 1-12 is/are pending in the application. 4a) Of the above claim(s) 12 is/are withdrawn from 5) Claim(s) is/are allowed. 6) Claim(s) 1-11 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or				
Application Papers				
9) The specification is objected to by the Examiner 10) The drawing(s) filed on is/are: a) access Applicant may not request that any objection to the december of Replacement drawing sheet(s) including the correction 11) The oath or declaration is objected to by the Examiner	epted or b) objected to by the Edrawing(s) be held in abeyance. See on is required if the drawing(s) is obj	e 37 CFR 1.85(a). sected to. See 37 CFR 1.121(d).		
Priority under 35 U.S.C. § 119				
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 				
Attachment(s) Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	ite		

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DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- Claims 1-11 are drawn to compounds and pharmaceutical compositions of Formula 1.
- II. Claim 12 is drawn to a method of treating a gastrointestinal disorder within the scope of compounds of Group I. An election of species is required if this group is chosen.

The inventions listed as Group I do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

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Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features...those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The special technical feature corresponding to Group I is a 1,2,4-triazolo[4,3-a]pyridine structure of Formula I.

The technical feature corresponding to the methods claims of Groups II is a method of treating a gastrointestinal disorder within the scope of compounds of Group I.

There is a significant difference in the between compounds/composition and methods of treating a disease/condition and method of treatment. These treatments of diseases/conditions and compounds/compositions are not considered equivalent.

The special technical feature of this invention is the common core found in Formula 1. This special technical feature, found in US 4,358,453 A as described by Bristol et al (see *Example*, column 7).

Therefore the above claims, are not so linked as to form a single general inventive concept and there is a lack of unity of invention because they lack a common core structure and the technical features present fail to define a contribution over the prior art. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper.

Therefore, since the claims do not relate to a single general inventive concept under PCT Rule 13.1 and lack the same or corresponding special technical features, the claims lack unity of invention and should be limited to only one invention.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete <u>must</u> include (i) an election of a invention to be examined even though the requirement

may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Election

During a telephone conversation with Sheldon McGee on October 25, 2007, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-11. Affirmation of this election must be made by applicant in replying to this Office action. Claim 12 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

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Rejoinder Advisory

The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double

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patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Effective November 1, 2007, if applicant wishes to present more than 5 independent claims or more than 25 total claims in an application, applicant will be required to file an examination support document (ESD) in compliance with 37 CFR 1.265 before the first Office action on the merits (hereafter "5/25 claim threshold"). See Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46715 (Aug. 21, 2007), 1322 Off. Gaz. Pat. Office 76 (Sept. 11, 2007) (final rule). The changes to 37 CFR 1.75(b) apply to any pending applications in which a first Office action on the merits (FAOM) has not been mailed before November 1, 2007. Withdrawn claims will not be taken into account in determining whether an application exceeds the 5/25 claim threshold. For more information on the final rule, please see http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/clmcontfinalrule.html.

In response to the restriction requirement set forth in this Office action, applicant is required to file an election responsive to the restriction requirement. Applicant may not file a suggested restriction requirement (SRR) in lieu of an election responsive to the restriction requirement as a reply. A SRR alone will not be considered a *bona-fide* reply to this Office action.

If applicant elects an invention that is drawn to no more than 5 independent claims and no more than 25 total claims, applicant will not be required to file an ESD in compliance with 37 CFR 1.265 that covers each of the elected claims. If the elected invention is drawn to more than 5 independent claims or more than 25 total claims,

applicant may file an amendment canceling a number of elected claims so that the elected invention would be drawn to no more than 5 independent claims and no more than 25 total claims.

If the restriction requirement is mailed <u>on or after</u> November 1, 2007, applicant is also required to file an ESD in compliance with 37 CFR 1.265 that covers each of the elected claims, unless the elected invention is drawn to no more than 5 independent claims and no more than 25 total claims taking into account any amendment to the claims. To avoid the abandonment of the application, the ESD (if required) and the election must be filed within **TWO MONTHS** from the mailing date of this Office action. The two-month time period for reply is extendable under 37 CFR 1.136.

If the restriction requirement is mailed <u>before</u> November 1, 2007, the election must be filed within **ONE MONTH** or THIRTY DAYS, whichever is longer, from the mailing date of this Office action. The time period for reply is extendable under 37 CFR 1.136. Furthermore, if the elected invention is drawn to more than 5 independent claims or more than 25 total claims taking into account any amendment to the claims, the Office will notify applicant and provide a time period in which applicant is required to file an ESD in compliance with 37 CFR 1.265 covering each of the elected claims or amend the application to contain no more than 5 independent elected claims and no more than 25 total elected claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms "imidazo, morpholino, aziridino, azetidino, pyrrolidino, pyrrolo, piperidino, piperazino" in claim 1, 4 and 7 is a relative term which renders the claim indefinite. The term "imidazo, morpholino, aziridino, azetidino, pyrrolidino, pyrrolo, piperidino, piperazino" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For examination purposes, the Examiner interpreted said terms to be represented by the properly acceptable suffix of "-yl". The proper recitation of said terms should be written as "imidazoyl, morpholinyl, aziridinyl, and so forth.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for R1 being C1-4 alkyl; R2 being C1-4 alkoxycarbonyl, carboxyl (-CO2H), -CO-NR31R32 where R31/R32=H, hydroxyl C1-4 alkyl, alkyl; and Ar being alkyl substituted phenyl, does not reasonably provide enablement for R1, R2 and Ar being the following. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to made the invention commensurate in scope with these claims.

R1 not enabled for:

R1 is hydrogen, 3-7C-cycloalkyl, 3-7C-cycloalkyl-1-4C-alkyl or fluoro-1-4C-alkyl,

R2 not enabled for:

R2 is halogen, fluoro-1-4C-alkyl, 2-4C-alkenyl, 2-4C-alkynyl, cyano, hydroxy-1-4C-alkyl, 1-4C-alkoxy-1-4C-alkyl, 1-4C-alkoxy-1-4C-alkoxy-1-4C-alkoxy-1-4C-alkyl, amino-1-4C-alkyl, mono- or di-1-4C-alkylamino-1-4C-alkyl, the radical Res-1-4C-alkyl or the radical -CO-NR31R32,

where

Res is a imidazo, morpholino, aziridino, azetidino, pyrrolidino, pyrrolo, piperidino, piperazino or a with R30 substituted benzylamino radical and the

radical Res is bonded via its nitrogen atom or one of its nitrogen atoms to the 1-4C-alkyl radical, where

R30 is 1-4C-alkyl, hydroxy-1-4C-alkyl, 1-4C-alkoxy, 2-4C-alkenyloxy, 1-4C-alkylcarbonyl, carboxy, 1-4C-alkoxycarbonyl, carboxy-1-4C-alkyl, 1-4C-alkoxycarbonyl-1-4C-alkyl, halogen or hydroxy,

R31 is hydroxyl, 1-7C-alkyl, hydroxy-1-4C-alkyl or 1-4C-alkoxy-1-4C-alkyl and

R32 is hydrogen, or 1-4C-alkyl,

or where

R31 and R32 together, including the nitrogen atom to which both are bonded, are a pyrrolidino, piperidino, piperazino, N-1-4C-alkylpiperazino, morpholino, aziridino or azetidino group,

Ar is not enabled for:

Ar is R4, R5, R6 and R7 substituted mono- or bicyclic aromatic residue selected from the group consisting of phenyl, naphthyl, pyrrolyl, pyrazolyl, imidazolyl, 1,2,3-triazolyl, indolyl, benzimidazolyl, furyl, benzofuryl, thienyl, benzothienyl, thiazolyl,

isoxazolyl, pyridinyl, pyrimidinyl, chinolinyl and isochinolinyl,

wherein

R4 is hydrogen, 1-4C-alkyl, hydroxy-1-4C-alkyl, 1-4C-alkoxy, 2-4C-alkenyloxy, 1-4C-alkylcarbonyl, carboxy, 1-4C-alkoxycarbonyl, carboxy-1-4C-alkyl, 1-4C-alkoxycarbonyl-1-4C-alkyl, halogen, hydroxy, aryl, aryl-1-4C-alkyl, aryl-oxy, aryl-1-4C-alkoxy, fluoro-1-4C-alkyl, nitro, amino, mono- or di-1-4C-alkylamino, 1-4C-alkylcarbonylamino, 1-4C-alkoxy-1-4C-alkoxycarbonylamino, 1-4C-alkoxy-1-4C-alkoxycarbonylamino or sulfonyl,

R5 is hydrogen, 1-4C-alkyl, hydroxy-1-4C-alkyl, 1-4C-alkoxy, 2-4C-alkenyloxy, 1-4C-alkylcarbonyl, carboxy, 1-4C-alkoxycarbonyl, carboxy-1-4C-alkyl, 1-4C-alkoxycarbonyl-1-4C-alkyl, halogen, hydroxy, aryl, aryl-1-4C-alkyl, aryl-oxy, aryl-1-4C-alkoxy, fluoro-1-4C-alkyl, nitro, amino, mono- or di-1-4C-alkylamino, 1-4C-alkylcarbonylamino, 1-4C-alkoxy-1-4C-alkoxycarbonylamino, 1-4C-alkoxy-1-4C-alkoxycarbonylamino or sulfonyl,

R6 is hydrogen, 1-4C-alkyl or halogen and R7 is hydrogen, 1-4C-alkyl or halogen,

wherein

aryl is phenyl or substituted phenyl with one, two or three same or different substituents selected from the group consisting of 1-4C-alkyl, carboxy, 1-4C-alkoxycarbonyl, halogen, trifluoromethyl, nitro, trifluoromethoxy, hydroxy and cyano,

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or a salt thereof

Pages 13-20 of the Specification describe starting materials and methods for synthesis of compounds wherein R1=C1-4 alkyl; R2 = C1-4 alkoxycarbonyl, carboxyl (-CO2H), -CO-NR31R32 where R31/R32=H, hydroxyl C1-4 alkyl, alkyl; and Ar = alkyl substituted phenyl, but does not describe or list any reagents wherein compounds can be used to synthesis compounds where R1, R2 and Ar as listed above.

Pursuant to *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), one considers the following factors to determine whether undue experimentation is required: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working

examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. Some experimentation is not fatal; the issue is whether the amount of experimentation is "undue"; see *In re Vaeck*, 20 USPQ2d 1438, 1444.

The analysis is as follows:

- (1) Breadth of claims: Scope of the compounds. Owing to the range of many variables, millions of highly substituted compounds are embraced.
- (2) The nature of the invention: The invention is a highly substituted 1,2,4-triazolo[4,3-a]pyridine compounds.
- (3) Level of predictability in the art: It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and chemical reactivity (which is affected by determinants such as substituent effects, bonding, molecular geometry, etc) is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).
- (4) Direction or Guidance: That provided is very limited. Applicant shows a general synthesis of compounds of application's general formula I. Pages 13-20 of the Specification describes starting materials and methods for synthesis of compounds wherein wherein R1=C1-4 alkyl; R2 = C1-4 alkoxycarbonyl, carboxyl (-CO2H), -CO-

NR31R32 where R31/R32=H, hydroxyl C1-4 alkyl, alkyl; and Ar = alkyl substituted phenyl, but does not describe or list any reagents wherein compounds can be used to synthesis compounds where R1, R2 and Ar as listed above. There is limited evidence in the Specification of the example compounds that only covers no or a small portion of the substituents claimed of formula 1. Thus, there is no specific direction or guidance regarding said compounds specifically mentioned in Scope.

The availability of the starting material that is needed to prepare the invention as claimed is at issue here...As per MPEP 2164.01 (b). A key issue that can arise when determining whether the specification is enabling is whether the starting materials or apparatus necessary to a make the invention are available. In the biotechnical area, this is often true when the product or process requires a particular strain of microorganism and when the microorganism is available only after extensive screening. The Court *in re Ghiron*, 442 F.2d 985, 991, 169 USPQ 723, 727 (CCPA 1971), made it clear that if the practice of a method requires a particular apparatus, the application must provide a sufficient disclosure of the apparatus if the apparatus is not readily available. The same can be said if certain chemicals are required to make a compound or practice a chemical process. *In re Howarth*, 654 F.2d 103, 105, 210 USPQ 689, 691 (CCPA 1981).

(5) State of the Prior Art: These compounds are substituted 1,2,4-triazolo[4,3-a]pyridine compounds wherein R1=methyl, =CH2-CN and R2=H and Ar=unsubstituted phenyl,

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which are well documented in the art. So far as the examiner is aware, no substituted 1,2,4-triazolo[4,3-a]pyridine compounds of general formula 1 wherein R1, R2 and Ar equals aforementioned substituents of any kind have been made or used.

- (6) Working Examples: Applicant shows examples 1-4 (pages 15-16) but no working examples were shown wherein R1, R2 and Ar equal aforementioned substituents have been made or used of any kind.
- (7) Skill of those in the art: The ordinary artisan is highly skilled, e.g. a masters or PhD level chemist.
- (8) The quantity of experimentation needed: Since there are very limited working examples as described above, the amount of experimentation is expected to be high and burdensome.

Due to the level of unpredictability in the art, the very limited guidance provide, and the lack of working examples, the Applicant has shown lack of enablement for the groups noted.

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Mabry, PhD whose telephone number is (571) 270-1967. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

IM

JAMES O. WILSON

UPERVISORY PATENT EXAMINER

VECHNOLOGY CENTER 1600